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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,911	01/22/2004	Hector F. DeLuca	1256-00943	6146
26753	7590	06/22/2006	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			QAZI, SABIHA NAIM	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/762,911	DELUCA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sabiha Qazi	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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**Non-Final Office Action**

Claims 29-38 are pending. No claim is allowed at this time.

Response to Remarks Filed on 4/3/2006

- The Applicants' arguments and reference to Frolik et al. were fully considered especially regarding oral administration, were found persuasive. A comparative data of unobviousness and/or unexpected results can overcome double patenting rejection. Rejection is maintained.
- Examiner respectfully disagrees that the reference does not teach the compounds without 25-hydroxy group. Claims are drawn to a method of treating metabolic bone disease by the compound (20S)-1alpha-hydroxy-2alpha-methyl-19-nor-vitamin D<sub>3</sub>, whereas the claims of the issued Patents are drawn to the same method of treating metabolic bone disease.
- Presently claimed method uses the (20S)-1alpha-hydroxy-2alpha-methyl-19-nor-vitamin D<sub>3</sub>, compound, which does not contain 25-hydroxy group. These compounds are generically taught by the cited references when R5 in claim 27 (US '559) represent H and not a hydroxy group. See for example claim 3 in US '410.
- The examples of the issued patents contain 25-hydroxy vitamin D compounds, and do not contain compounds no 25- hydroxy group.

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-31 of DELUCA et al '410 (US Patent No. 5,945,410) and claims 27-37 of DELUCA et al '559 (US Patent No. 6,127,559). Although the conflicting claims are not identical, they are not patentably distinct from each other because presently claimed invention is obvious when, in the references, R6 is alkyl and R5 is H. Presently claimed compound contains a methyl group at R6 (in reference, it is an alkyl). The method of treating metabolic bone disease has been claimed in both references.

Presently claimed invention is drawn to a method of treating metabolic bone disease by the compound (20S)-1alpha-hydroxy-2alpha-methyl-19-nor-vitamin D<sub>3</sub>, whereas the claims of the Patents cited above are drawn to the same method of treating metabolic bone disease.

It would have been obvious to one skilled in the art to prepare additional compounds useful for the treatment of metabolic bone disease because the reference teach the uses of these vitamin D compounds. Presently claimed method uses the (20S)-1alpha-hydroxy-2alpha-methyl-19-nor-vitamin D<sub>3</sub> compound, which does not contain 25-hydroxy group. These compounds are generically taught by the cited references when R5 in claim 27 (US '559) represent H and not a hydroxy group. See for example claim 3 in US '410.

#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA PH.D  
PRIMARY EXAMINER